

**REMARKS**

Claims 15 and 31 have been amended to address concerns of the Examiner. The amendments are fully supported by the specification, do not narrow the scope of the claims, and do not add new matter.

New claim 33 is fully supported by the specification, e.g. on page 5, lines 15-26. No new matter is added.

Claims 15-17, 22-23 and 30-33 are pending.

**The indefiniteness rejection**

Claims 15 and 31, as amended, have correct antecedent basis. Withdrawal of the rejection is requested.

**Rejection under 35 U.S.C. §102**

Claims 15-17, 23 and 27-30 were rejected under 35 USC § 102(e) as allegedly being anticipated by Focke et al. (USP 7,244,432). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

The Examiner has taken the position that Focke et al., under the broadest reasonable interpretation, discloses enteric administration. Applicants disagree with this interpretation, for reasons of record. Furthermore, in order to advance prosecution, new claim 33 recites a number of components that are not disclosed by Focke et al.

To anticipate a claim, a reference must teach each and every element of the claim. That is clearly not the case here, at least for claim 33. Withdrawal of the rejection is requested.

Claims 15-17, 23, and 27-32 were rejected under 35 USC § 102(b) as allegedly being anticipated by Tanabe et al (BBRC 223:492, 1996). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

It is the Examiner's position that Tanabe et al. teach a pharmaceutical composition comprising a mixture of hydrolyzed peptides. However, Applicants disagree with this interpretation, for reasons of record. Furthermore, applicants respectfully submit that Tanabe et al. fail to disclose a *pharmaceutical* formulation. The experiments presented in Tanabe et al. are performed *in vitro*, rather than in a subject. Therefore, the reference does not disclose a pharmaceutical composition, as is presently claimed.

Furthermore, the reference certainly does not disclose the elements recited in new claim 33.

To anticipate a claim, a reference must teach each and every element of the claim. That is clearly not the case here. Withdrawal of the rejection is requested.

#### Rejections under 35 U.S.C. §103

Claims 15-17, 22, 23 and 27-30 were rejected under 35 USC § 103(a) as allegedly being unpatentable over Focke et al. and Marx (USP 5,898,037). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

Applicants disagree with this rejection, for reasons of record. Applicants believe that this reference does not suggest or disclose the pending claims, e.g. new claim 33. For example, there is no suggestion or disclosure in the reference to include the elements recited in claim 33. The Marx patent fails to remedy this omission. Accordingly, the combination fails to provide a motivation to alter the composition taught by Focke et al to include these added elements, and thus does not render claim 33 obvious. Withdrawal of the rejection is respectfully requested.

Claim 22 was rejected under 35 USC § 103(a) as allegedly being unpatentable over Tanabe et al. and Marx (USP 5,898,037). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

As detailed above, Tanabe et al. fails to teach each and every element of the independent claims, namely a *pharmaceutical* composition. Furthermore, the reference does not suggest or disclose a method of administering the composition to a subject; therefore, the reference does not provide a motivation, with a reasonable expectation of success, to administer the composition to a subject, in particular to administer it enterically. The secondary reference, Marx, fails to remedy these omissions. Accordingly, the combination fails to provide a motivation to alter Tanabe et al to disclose a pharmaceutical composition, and therefore fails to render obvious claim 22.

Withdrawal of the rejection is respectfully requested.

In view of the above arguments and amendments, applicant believes the pending application is in condition for allowance, which action is respectfully requested.

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Respectfully submitted,

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